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10/525,373	01/17/2006	Vladimir Sheiman	XA-11616	5191

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MCLEAN, VA 22102-3833

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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3771

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/525,373	Applicant(s) SHEIMAN, VLADIMIR	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/21/2010 & 10/8/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-19, 21, 24-30, 34, 39-50, and 51 (second occurrence of 49) is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-19, 21, 24-30, 34, 39-43 & 44-49, and 51 (second occurrence of 49) is/are rejected.
- 7) ☒ Claim(s) 44 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/8/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's amendment filed September 21, 2010. As directed by the amendment, claims 18, 30-31, 34 and 39 have been amended. Claims 20, 22-23, 32-33, and 35-38 have been cancelled and new claims have 40-50 have been added. Thus, claims 18-19, 21, 24-31, 34, and 39-50, as well as the second occurrence of claim 49 which has been renumbered claim 51) are pending in this application.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Applicant has presented claim 49 twice and the misnumbered second appearance of claim 49 been renumbered claim 51. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18-19, 21, 24-27, 30-31, 34, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa (4,410,139) and further in view of

KHMELEV et al (RU 2070062 C1), based on the English translation provided by The McElroy Translation Company for the United States Patent and Trademark Office (PTO 09-2827), herein referred to as KHMELEV.

Regarding claim 18, Nishikawa discloses a nebulizer (figure 6) comprising a container (lower portion of 1) adapted to contain a liquid (A) to be nebulized; a tubular energy transmitter (30 & 31) including an acoustic transmitter pipe (30 as described in col. 3, lines 25-30) having one end (lower end) immersed in the liquid proximate and spaced from the container (via 32); an aerosol tube (middle portion of 1) around a portion of the acoustic transmitter pipe (30); an energy source (4) being operatively coupled to the container (lower portion of 1) for nebulization of the liquid (A) and being **configured** for transmission of energy to a focal region (C) of the liquid proximate (very near; close) said one end of the acoustic transmitter pipe(30) whereby said liquid (A) is forced toward the upper end of the nebulizer device and nebulized within the aerosol tube.

However, Nishikawa lacks the specific teaching of the focal region of the liquid proximate one end of the acoustic transmitter pipe whereby the liquid is forced toward an opposite end of the acoustic pipe.

KHMELEV teaches an ultrasonic nebulizer (figure) with a focal region (20) proximal to the tubular energy transmitter pipe (17) whereby the liquid is forced toward an opposite end of the pipe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer device disclosed by Nishikawa by

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utilizing a bowl shaped ultrasonic transducer, as taught by KHMELEV, that would direct the focal region to an area proximate to the tubular energy transducer pipe and then force liquid toward the opposite end of the transducer pipe in order to form a nebulizer that would assure the liquid is completely used and that there will be high stability in the disperse composition of the aerosol and its density.

Regarding claim 19, KHMELEV teaches the energy source (2, 3, and 4) is positioned below the container (7).

Regarding claim 21, the acoustic transmitter pipe (30 of Nishikawa) is positioned so that said one end is proximate the bottom of the container. See: figures 6 & 7 of Nishikawa.

Regarding claim 24, the combined dereferences teach the internal diameter of the aerosol tube (upper portion of 1 of Nishikawa) is greater than an outer diameter of the acoustic transmitter pipe (30 of Nishikawa) at the opposite end of the tubular energy transmitter.

Regarding claim 25, the aerosol tube (upper portion of 1 of Nishikawa) of the combined references is positioned so that it is substantially coaxial with the tubular energy transmitter (30 of Nishikawa).

Regarding claim 26, the nebulizer of the combined references has an aerosol tube (upper portion of 1 of Nishikawa) that is connected to the opposite end of the tubular energy transmitter (30 of Nishikawa via 31, 32 and lower portion of 1).

Regarding claim 27, the device of the combined reference has an energy source (2, 3, and 4 of KHMELEV) that vibrates the liquid proximate the opposite end of the acoustic transmitter pipe (30 of Nishikawa).

Regarding claim 30, the device of the combined references uses an energy source that comprises an ultrasonic transducer (2, 3, and 4 of KHMELEV).

Regarding claim 31, the device of the combined references, uses an ultrasonic transducer (2, 3, 4) that has a concave shaped surface. See figure of KHMELEV.

Regarding claim 34, the internal diameter of the acoustic transmitter pipe (30 of Nishikawa) is **substantially** equal to a diameter of the focal region (20 of KHMELEV).

Regarding claim 40, it is the examiner's position that the tube forming the tubular energy transmitter (30 of Nishikawa) inherently has a higher acoustic impedance than the liquid.

Regarding claim 41, the ultrasonic transducer (2, 3, and 4) of KHMELEV is a bowl-shaped ultrasonic transducer.

Regarding claim 42, both references (3 of Nishikawa or 13, 14, 15 of KHMELEV) have inlet for replenishment of air during nebulization of the liquid.

Regarding claim 43, the device of the combined references has an energy source (2, 3, 4 of KHMELEV) and said acoustic transmitter pipe (30 & 31 of Nishikawa) are configured such that a guided spout (21 of KHMELEV) of said liquid (8 of KHMELEV) to be nebulized is emitted from said opposite end of said acoustic transmitter pipe (as shown in figure 6 of Nishikawa, the liquid projects above the tube).

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5. Claims 28-29 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa (4,410,139) and further in view of KHMELEV et al (RU 2070062 C1), based on the English translation provided by The McElroy Translation Company for the United States Patent and Trademark Office (PTO 09-2827), herein referred to as KHMELEV, as applied to claim 18 above, and further in view of Sheiman (WO 99/42145 A1).

The combined references teach all the limitations of claim 28, except that the aerosol tube opens at its upper end into an expansion chamber which in turn communicates with an outlet duct (36).

Sheiman teaches an aerosol tube (30) which opens at its upper end into an expansion chamber (28) which in turn communicates with an outlet duct (38).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the ultrasonic nebulization device disclosed by the combined references by placing an expansion chamber at the outlet of the aerosol tube to form a nebulizer that allows for only the smallest particle sized particles to exit the nebulizer.

Regarding claim 29, Sheiman teaches the expansion chamber (inside 28) is adapted (via 31) to return non-nebulized liquid to the container via a drainage pipe (31).

Regarding claim 39, Sheiman discloses a partition wall (wall of 38 within expansion chamber) located to one side of the expansion chamber (28) to separate the outlet duct (38) from the acoustic transmitter pipe (30 of Nishikawa).

6. Claims 45-49 and 51 (second occurrence of claim 49) are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheiman (WO 99/42145 A1) and further in view of Nishikawa (4,410,139) and Applicant's admitted prior art (figure 1).

Sheiman discloses a nebulizer (figure 2) comprising a reservoir (tank) for containing an initial volume of a liquid (27) to be nebulized, said initial volume (27) of said liquid having a liquid surface located at an initial surface level (see liquid level inside tank in figure 2) within said reservoir; a tubular sound-transmitting conduit (30) for said liquid, said conduit having a liquid inlet end (bottom) positioned within said reservoir (tank) at a liquid (liquid inside 30) inlet location, and a liquid outlet end positioned at a nebulizing location above said initial surface level (see tube 30 with outlet above the fluid level in the tank); a source of ultrasonic energy (18) configured to transmit said ultrasonic energy to a focal region just below conical shape liquid flowing upward through tube 30) located generally on an axis of said conduit (see figure 2 of Sheiman) adjacent to said inlet end of said conduit; said conduit (30) being configured to contain a column of liquid extending from said liquid inlet (lower end of conduit) end to said liquid outlet (upper end of conduit) end and to transmit said ultrasonic energy from said focal region to said liquid outlet end, at least through said column of liquid, and said source of ultrasonic energy (18) being operative to supply said ultrasonic energy to said focal region with sufficient intensity to advance said liquid to be nebulized through said conduit and out said liquid outlet end and to nebulize said liquid exiting from said outlet end.

However, Sheiman lacks the conduit being immersed in the fluid and the specific teaching that a bowl shaped ultrasonic transducer has a focal point in the fluid which causes the fluid to extend upwardly.

Nishikawa teaches an ultrasonic nebulizer with a conduit that extends from being immersed in the liquid to outside the liquid. See: figures 6-8.

Applicants admitted prior art shows a bowl shaped transducer with a focal point that causes fluid to project upwardly into an aerosol tube.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device disclosed by Sheiman, by using a conduit that extends below the surface of the fluid to be nebulized, as taught by Nishikawa and had the bowl shaped transducer focal region close to the surface of the fluid to be nebulized, as taught by applicant's admitted prior art, in order to form a nebulizer that delivers nebulized fluid directly to a nebulization chamber wherein non-nebulized fluid can be directed back to the tank.

Regarding claim 46, the nebulizer disclosed by Sheiman has a reservoir (tank) has an interior bottom surface and said focal region is adjacent said interior bottom surface.

Regarding claim 47, Sheiman discloses the source of ultrasonic energy (18) as a concave transducer.

Regarding claim 48, the conduit of the combined references (30 of Sheiman modified by (30 and 31 or 40 and 41 of Nishikawa) has a wall (tube wall) configured to transmit said ultrasonic energy from said liquid inlet end to said liquid outlet end.

Regarding claim 49, the nebulizer of the combined references utilizes ultrasonic energy that is directed generally upward along said axis of said conduit. See: figure 2 of Sheiman or Applicant's admitted prior art, figure 1.

Regarding claim 51 (second occurrence of claim 49), the nebulizer of the combined references is a source of ultrasonic energy and the modified conduit is configured such that a guided spout (as shown in figure 2 of Sheiman inside 30 or applicant's admitted prior art 22) of said liquid to be nebulized is emitted from said liquid outlet end of said conduit (as shown in figure 2 of Sheiman wherein the liquid strikes the top of the nebulization chamber).

Response to Arguments

7. Applicant's arguments filed September 21, 2010 have been fully considered but they are not persuasive.

Regarding applicant's argument that they do "not see in Nishikawa any mention of a focal region, and Nishikawa's 'projection (C)' is evidently proximate to the upper end of cylinder 30, not to the lower end thereof" it is the examiner's position that the focused radiation (via the cylinder 30 and disk 31) results in formation of the upwardly projection (C) and the subsequent aerosol droplets. Moreover, the bowl shaped acoustic transducer of KHMELEV shows a focal point as being within the liquid. Thus, the modified structure of the device taught by the combined references, utilizing a bowl shaped ultrasonic transducer, as taught by KHMELEV, which would direct the focal region to an area proximate to the tubular energy transducer pipe and then force liquid toward the opposite end of the transducer pipe.

Regarding applicant's argument on page 12, first full paragraph, that the end of KHMELEV's sleeve (17) that is proximal to his focal region (20) is not immersed in the liquid to be nebulized as recited in Claim 18, the examiner respectfully agrees. However, Nishikawa was used to teach a tube that is immersed in the liquid.

Regarding applicant's argument that there is no teaching or suggestion in the applied references to configure a source of acoustic energy to a focal region of the liquid proximate (very near; close) an immersed end of an acoustic transmitter pipe whereby the liquid is forced toward an opposite end of the acoustic transmitter pipe and nebulized within the aerosol tube, the examiner respectfully disagrees. Both Nishikawa and KHMELEV teach ultrasonic nebulizers that nebulizer liquids and force the liquid, and nebulized liquid, from one end of a tube to the other end of the tube and the combined references disclose a nebulizer that would assure the liquid is completely used and that there would be high stability in the disperse composition of the aerosol and its density.

8. Regarding applicant's assertion, in the last paragraph on page 12, that claims 18-19, 21, 24-31, 34, 39 and 40 are allowable over the combined references, the examiner respectfully disagrees for the reasons set forth above.

9. Regarding applicant's assertion, in the second full paragraph on page 13, that claims 28-29 and 39 are allowable because the Sheiman reference does not remedy the deficiencies of the Nishikawa and KHMELEV references has not been found convincing. The combined references do teach the limitations of independent claim 18,

and Sheiman teaches the limitations of dependent claims 28-29 and 39, as discussed above.

Allowable Subject Matter

10. Claims 44 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767